Questions as described by OPARM and OCFO

- Updates to the IRIS program (recent improvements, obstacles, changes in processes) over the past year
    - How these changes address stakeholder concerns (such as GAO/NAS recommendations or directives from Congress)?

UPDATES TO THE IRIS PROGRAM

Changes in Leadership

- In January 2017, EPA appointed new leadership to the National Center for Environmental Assessment and to its IRIS Program.
    - With significant experience in the chemical industry, and formerly the Director of ORD's Chemical Safety for Sustainability National Research Program, the new NCEA Director, Tina Bahadori, brings knowledge of TSCA, innovative applications of computational toxicology, and exposure science.
    - As a recognized leader in systematic review, automation, and chemical evaluations, the new IRIS Program Director, Kris Thayer, brings experience in early partner and stakeholder engagement and input, and demonstrated actions to increase capacity and transparency in assessments.
    - A critical hire in FY2017 was the Assistant Center Director for Scientific Support, Emma Lavoie, dedicated to engaging EPA program and regional offices and states, with the goal to improve NCEA's ability to be responsive to dynamic needs.

A Portfolio Approach

- NCEA assessments support policy and regulatory decisions for EPA's programs and regions, state agencies, and tribal nations. NCEA is developing a portfolio of chemical evaluation products that optimize the application of the best available science and technology. Fit for their intended purpose or decision context, these products are being tailored for use by a diversity of clients, including EPA program and regional offices, other federal agencies, states, and tribal nations.
- The IRIS Multi-Year Agenda, issued in December 2015, provides an outlook on the planned assessments that were identified in collaboration with EPA program and regional offices, and scaled to the projected resources.
    - Starting in 2018, however, the IRIS Program will reconfirm this information annually to ensure that it remains responsive. The modernization of TSCA, and emergence of other urgent EPA and Administrator priorities, highlighted the need for NCEA to incorporate nimbler approaches. This will allow NCEA to a) adjust to EPA's strategic regulatory and policy directions, while scientifically remaining ahead of this curve; b) manage tactically by ensuring that the order/timing/priorities of its assessment activities are consistent with both short-term and long-term goals; and c) work proactively and responsively to translate and integrate the science and its tailored 'fit-for-purpose' products.
- To test these nimbler approaches, in 2017, NCEA evaluated the Agenda relative to emerging EPA priorities, and made important adjustments by:
    - Building a more proactive pipeline with EPA's Office of Pollution Prevention and Toxics (OPPT) to provide the support required for TSCA implementation. Similar interaction with other program offices is underway, such as work with the Office of Air and Radiation (OAR) to support response to court-ordered requirements under the Residual Risk Assessment Program.
    - A pilot for targeted assessments structured as case studies of pragmatic systematic review methodologies/protocols and related automation tools.

  - IRIS is developing assessment plans (IAPs) that focus on scoping and problem formulation, define user needs, and frame the scientific questions prior to draft development. Scientific and public input will be sought early in the process to promote transparency and identify key scientific issues.
- These approaches were presented for consultation with the SAB CAAC in September 2017.

Program/Project Management

- In FY2017, NCEA deployed program and project management (PM) for the IRIS Program. This includes working with chemical managers to develop timelines and a system that tracks the array of IRIS products in development, allowing the IRIS Program to more effectively and efficiently utilize human resources across assessment projects and ensure timely delivery of products. NCEA has developed tools for tracking decisions and actions taken, and has ongoing training for staff and managers in the use of project management (PM) tools and systems.

Operationalizing Systematic Review

- NCEA also launched an effort to adapt automation and machine learning tools to the Systematic Review workflow. The new IRIS Director is an international leader in this field and has, in February and March, provided extensive training to risk assessors in NCEA in accelerated and fit-for-purpose Systematic Review.
- A Community of Practice in Systematic Review was established in April 2017 to broadly engage and share best practices, as well as provide similar training across EPA's risk assessment community.
- NCEA is also collaborating with EPA's National Center for Computational Toxicology (NCCT) to link the architecture of NCEA's assessment databases and literature management tools (including *Health and Environmental Research Online*/HERO) with the RapidTox Dashboard being developed by NCCT in ORD's Chemical Safety for Sustainability (CSS) National Research Program. This Dashboard is being evaluated through a series of focused case studies with EPA's program offices. When developed, the RapidTox Dashboard can be used to inform assessment development and fill gaps in assessments, especially for data poor chemicals. It can also incorporate diverse data streams, including data from non-animal testing strategies, to develop assessment products for chemicals that are lacking assessments. RapidTox can help prioritize the data gaps in assessments and inform where resources should be invested to generate additional data. The National Academies Report, *Using 21st Century Science to Improve Risk-Related Evaluations* (http://dels.nas.edu/Report/Using-21st-Century-Science-Improve/24635?bname=best) provided additional guidance for implementing this approach through structured case studies.

ADDRESSING STAKEHOLDER CONCERNS

GAO: The GAO reports on the IRIS program have been the subject of much misinterpretation. For this reason, Alfredo Gomez, GAO Director of Natural Resources and the Environment, has indicated that he is available (202-512-3841; gomezj@gao.gov) to clarify the GAO findings.

In the 2017 GAO High Risk Report, GAO stated:

> EPA's "ability to effectively implement its mission of protecting public health and the environment is critically dependent on assessing the risks posed by chemicals in a credible and timely manner. Such assessments are the cornerstone of scientifically sound environmental decisions, policies, and regulations under a variety of statutes, such as the Safe Drinking Water Act, the Toxic Substances Control Act (TSCA), and the Clean Air Act. EPA conducts assessments of chemicals under its Integrated Risk Information System (IRIS) program." (p. 417)

GAO's identification of IRIS as a program in need of broad-based transformation reflects their evaluation that IRIS's work is critical to support Agency activities under not only the amended TSCA, but other statues as well.

GAO also observed that, "EPA needs to continue to determine for both the IRIS and TSCA programs if it has adequate capacity to resolve this high-risk area [capacity]. EPA needs to work with Congress to ensure that the resources dedicated to IRIS and TSCA activities are sufficient to maintain a viable IRIS database of chemical assessments, and effectively implement TSCA reform activities." (p. 417)

Additionally, GAO noted the following: "EPA's IRIS database is intended to provide the basic information the agency needs to determine whether it should establish controls to, for example, protect the public from exposure to toxic chemicals in the air, in water, and at hazardous waste sites." (p. 422)

NAS: This is what the NAS said in its 2014 report: "Overall, the committee finds that substantial improvements in the IRIS process have been made, and it is clear that EPA has embraced and is acting on the recommendations in the NRC formaldehyde report. The NRC formaldehyde committee recognized that its suggested changes would take several years and an extensive effort by EPA staff to implement. Substantial progress, however, has been made in a short time, and the present committee's recommendations should be seen as building on the progress that EPA has already made." [p.9]

" . . . the IRIS program has moved forward steadily in planning for and implementing changes in each element of the assessment process. The committee is confident that there is an institutional commitment to completing the revisions of the process . . . Overall the committee expects that EPA will complete its planned revisions in a timely way and that the revisions will transform the IRIS Program." [p.135]

Two upcoming NAS activities:

1) A review of the IRIS program to evaluate progress since 2014
2) A peer review of the formaldehyde assessment, which also includes process and programmatic activities.

Congressional oversight: Per 2017 appropriations language, IRIS (p. 63), EPA to convene an interagency working group of relevant executive branch stakeholders and co-chaired with OIRA (https://www.congress.gov/114/crpt/srpt281/CRPT-114srpt281.pdf to review compliance with NAS 2014 report. Report to be issued by October 2017.

- Interagency Working Group established
- Co-chaired by Jim Kim/OIRA and Kris Thayer/EPA
- Met three times, will move to quarterly meetings
- Update Report to Congress will be prepared
- NAS commissioned to evaluate IRIS progress

- Plans for FY 2018 provided the current FY 2018 House marks (closer to FY 2017 Enacted compared to the FY 2018 President's Budget, but still a reduction across the Science and Technology account)
    - Include discussion of TSCA and how the IRIS program is supporting new TSCA authorities moving forward
        - What is the overlap between IRIS and TSCA and what are the benefits/challenges in the 2 programs working closely together

Plans for FY18: Training staff to bring more of work in-house; automation and pragmatic systematic review; portfolio approach; collaborations and partnerships

Current support for TSCA: Escalated support in the last several months with 15-20 staff currently working in direct support of the first 10 chemical assessments.

- Right now, staff are providing chemical specific expertise, in addition to toxicology and epidemiology expertise, for scoping and evaluating health hazard information; quality checks work completed by contractors; providing training and assistance in implementing best practices of systematic review and evidence synthesis, and develop automated software workflows directed at expediting the pace and throughput of TSCA assessments.
- Support of TSCA will increase as evaluations are started beyond scoping stages, and as OPPT works to meet the statutory requirements for having 20 chemical assessments in development at a time.
- For each chemical, IRIS will provide a team of approximately 5-7 experts in addition to support staff and database management support:
- Chemical specific expertise; Epidemiologists; Toxicologists; Biologists, including neurodevelopmental (children's) health; Dose-response analysis and statistical expertise
- Expertise to help evaluate alternative testing methods for risk assessments
- **Systematic review**/software automation expertise
- Team **HERO**, other database and informatics/IT support
- **Project Management**

IRIS & TSCA: There is an expectation that TSCA, modernized under the Lautenberg Act, can replace the functions of IRIS. But TSCA addresses chemicals in commerce.

- It does NOT support other activities such as site cleanups, drinking water evaluations, etc. IRIS provides these types of support across EPA, and for states and tribal nations.
- Chemical evaluations under TSCA do not provide the reference values statutorily required by other programs.
- IRIS also evaluates naturally occurring chemicals (like manganese) and chemical degradants.

Challenges and Benefits: Consistency, improved timeline, operationalizing systematic review

- Discussion of the FY 2019 Request
    - How would the IRIS program change under a large budget (-60%) and FTE reduction (-50%)?
    - What would be the consequences of implementing the program at these low resource levels?

IRIS Bottom Line: In order for ORD to maintain a minimal 'functioning' IRIS program, ORD will need S&T resources for approximately 40.0 FTE's (a 30% reduction from current levels of 58.3 FTEs) and $2.5M extramural resources (a 50% reduction from current levels of $5M).

- Information on how other EPA offices/programs utilize IRIS values, and in what ways
  - Can include non-EPA stakeholders (other agencies, industries, organizations, countries, etc.)

How EPA offices/program utilize IRIS values

IRIS was created in 1985 to address the confusion and inconsistency that arose previously when different EPA programs conducted separate assessments that resulted in different hazard conclusions or toxicity values for the same chemical. IRIS assessments are the top tier products in the hierarchies used by EPA Programs and Regions for using assessments as the basis for their programmatic decisions.

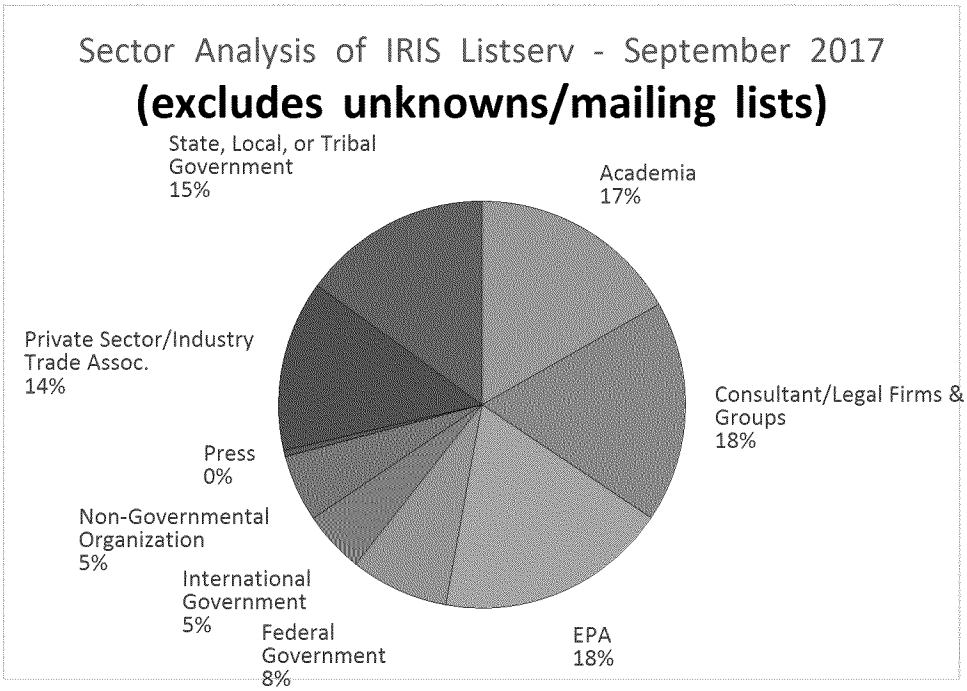
- **OLEM:** OLEM does not conduct its own hazard and dose-response assessments. OLEM relies on IRIS to inform clean-up decisions at contaminated Superfund and hazardous waste sites. IRIS assessments provide toxicity values to inform site-specific cleanups.
- **OAR:** IRIS assessments are key to the Risk and Technology Reviews (RTR) required under the Clean Air Act Title III (there is currently a court-ordered deadline to review 20 source categories in 3 years).
- **OW:** IRIS assessments are used to set health advisories, maximum contaminant levels, and other actions in the Office of Water. OW nominates and prioritizes chemicals for IRIS assessment that are high-profile and more controversial and that would take additional time and resources to complete. They also look to IRIS experts for support on actions based on completed assessments; perchlorate is a recent example. IRIS experts also provide support on high profile chemical activities in the agency - lead and PFAs are recent examples.
- **OCSPP/OPPT:** IRIS staff are currently working in direct support of the first 10 chemical assessments, providing chemical specific expertise for scoping and evaluating health hazard information, quality checks for work completed by contractors, and training and assistance in implementing best practices of systematic review and evidence synthesis. IRIS staff are also helping to develop automated software workflows directed at expediting the pace and throughput of chemical assessments. IRIS is helping OPPT implement efficiencies to meet their TSCA timelines; additionally, IRIS is aiming to shorten NCEA's chemical evaluation timeline to ~2 years (pre- peer review) to be more consistent with TSCA timelines.
- **Regions, States and Tribes:** IRIS provides a critical part of the scientific foundation for decision-making by EPA's regional offices, states, and tribes under an array of environmental laws, but in particular to clean up, revitalize and return land back to communities. In addition, IRIS provides localized technical assistance and scientific expertise on human health risk assessments. This includes direct support in cases of emergencies and other rapid response situations.
- **Other Agencies:** IRIS assessments are important resources for other federal, state, and international agencies. For example, DOD policy instructions for the management of emerging contaminants identify IRIS assessments as the top tier of chemical information to be used in conducting risk assessments for contaminated sites (DODI 4715.18). International agencies, such as Health Canada and RIVM/Netherlands use IRIS assessments to inform their risk assessment/management strategies.
- **Urgent Situations:** IRIS experts also frequently provide continual support to risk managers and regulators in

support of priority and emergency issues in the regions, states, and tribes.

- **IRIS is the only federal program to provide toxicity values for both cancer and non-cancer effects, including quantifying risk values (cancer slope factor).**

IRIS Listserv Analysis (Sept 2017)

Sector	Count	Percentage
Academia	366	17
Consultant/Legal Firms & Groups	384	18
EPA	403	18
Federal Government	170	8
International Government	107	5
Non-Governmental Organization	116	5
Press	11	0
Private Sector/Industry Trade Assoc.	296	14
State, Local, or Tribal Government	328	15



This analysis excludes signups by other mailing lists (which aren't attributed), and personal email accounts without affiliation (some people sign up for the IRIS list on their work and home accounts). **In total, there are 3902 signups for the IRIS listserv.**